Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P023P02	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/002601	International filing date (*day/month/year*) 05 March 2003 (05.03.2003)	Priority date (*day/month/year*) 29 March 2002 (29.03.2002)
International Patent Classification (IPC) or national classification and IPC A61K 48/00, 45/00, 9/51, 9/08, 38/45, A61P 1/16, 35/00		
Applicant JAPAN SCIENCE AND TECHNOLOGY CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
31 July 2003 (31.07.2003)	20 November 2003 (20.11.2003)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/002601

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIM[redacted]RY EXAMINATION REPORT

International application No. [redacted]CT/JP03/02601

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 7

because:

☒ the said international application, or the said claims Nos. 7 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject matter of claim 7 relates to a method for treatment of the human body by therapy, which does not require an international preliminary examination by the International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 7.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIM[redacted]RY EXAMINATION REPORT

International application No. [redacted]T/JP03/02601

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-6	NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations

Document 1: WO, 01-64930, A1 (Japan Science and Technology Corp.), 7 September, 2001 (07.09.01), & EP, 1262555, A1, & JP, 2001-316298, A

Document 2: WO, 01-93836, A1 (T. Boulikas), 13 December, 2001 (13.12.01), full text, e.g., claim 9, & AU, 2001-75423, B, & EP, 1292284, A2, & US, 2003-72794, A

Document 3: Induction of Sensitivity to Ganciclovir in Human Hepatocellular Carcinoma Cells by Adenovirus-Mediated Gene Transfer of Herpes Simplex Virus Thymidine Kinase, (C. Qian, et al.), Hepatology, 1995, Vol. 22, pages 118-123

Document 1 describes hollow nanoparticles [illegible] a hepatitis B virus (HBV) surface antigen protein, and also describes that a gene to code for [illegible], for cancer treatment and be so integrated that it can be expressed is contained, as a substance to be [illegible] into a cell, in the said hollow nanoparticle (page 8, line 4 to page 9, line 3, Examples G and H). The document also describes that, for such hollow nanoparticles, molecules that can bond to specific cell-surface molecules, e.g., EGF, are provided to exist on the surface of particles in order to increase their specificity to target cells (Examples D-F, 6-9).

In view of such descriptions in document 1, a person skilled in the art could have easily conceived of the ideas of (1) preparing hollow nanoparticles where molecules to bond to specific cell-surface molecules exist on the surface, (2) adopting as a substance to be introduced into such particle, (a) a well-known HSV1 (tk) gene effective for treatment of cancer of hepatic cells, e.g., those described in documents 2 and 3 or (b) other genes for cancer treatment that had been well known prior to the priority date of the present application, (3) having one of those genes contained in a hollow nanoparticle in a manner that it can be expressed, and (4) applying drugs having the obtained particles as an active ingredient for treatment of diseases such as cancer in a desired target region of the body.

Accordingly, the subject matters of claims 1-6 do not appear to involve an inventive step in view of document 1 or documents 1-3.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : V

If the subject matter of any of the said claims was limited to combinations of specific conditions, in other words, adopting specific ones for "specific cell-surface molecules" and specific ones for a "substance to be introduced into cells" and applying the product for specific diseases in specific target regions of the body, whereby it was revealed that specific excellent therapeutic effects beyond expectation based on the descriptions in the documents had been observed, the subject matter would have appeared to involve an inventive step. However, in view of the descriptions in the said claims, none of them sets forth only the specific combinations of conditions whereby the above-mentioned specific excellent therapeutic effects were observed, as a feature to distinguish them from others.